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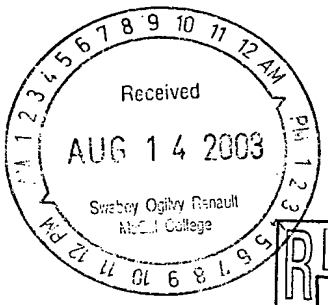

August 11, 2003

DUE ON FEB 11 2004 DL

Amendment

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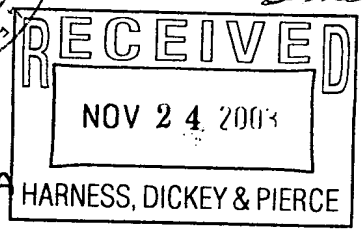

Application No.	:	**2,344,867** 5430-50CA
Owner	:	JOMAA PHARMAKA GMBH
Title	:	**USE OF ORGANOPHOSPHOROUS COMPOUNDS FOR PRODUCING MEDICAMENTS FOR THE THERAPEUTIC AND PROPHYLACTIC TREATMENT OF INFECTIONS OR AS A FUNGICIDE, BACTERICIDE OR HERBICIDE FOR PLANTS**
Classification	:	A61K-31/00
Examiner	:	**Wesley Sharman**

IN ACCORDANCE WITH SUBSECTION 30(2) OF THE PATENT RULES, YOU ARE HEREBY NOTIFIED OF A REQUISITION BY THE EXAMINER. IN ORDER TO AVOID ABANDONMENT UNDER PARAGRAPH 73(1)(A) OF THE PATENT ACT, A WRITTEN REPLY MUST BE RECEIVED WITHIN 6 MONTHS AFTER THE ABOVE DATE.

This application has been examined as originally filed.

The number of claims in this application is 14.

A search of the prior art has revealed the following:

References Applied:

Japanese Patent Document

61106504	May 24, 1986	Yamaji et al.

Canadian Patent Documents

1118784	Feb. 23, 1982	Maier
1312607	Jan. 12, 1993	Parsons et al.
2089650	Mar. 5, 1992	Kleiner
2260898	Jan. 29, 1998	Reiter

Yamaji et al. disclose N-substituted aminoalkylphosphinic acid derivatives and their use as herbicides.

Maier discloses glycylmethylphosphinic acid derivatives and their use as a herbicide.

Parsons et al. disclose carbapenem antibiotics based on new 3-(1-aminoalkylphosphinyl)-(2-substituted)propionic acids.

Kleiner discloses aminomethanephosphonic acid derivatives and their biological activity.

Reiter discloses aminoalkylphosphonic acid derivatives and their use, either alone or in combination with other pharmaceutically active compounds, against AIDS, sepsis, septic shock, periodontal disease and other diseases and infections.

The examiner has identified the following defects in the application:

Claims 1-6 do not comply with Paragraph 28.2(1)(b) of the Patent Act. Yamaji et al. disclosed the claimed subject matter before the claim date wherein the compounds are used as a herbicide.

Claim 1 does not comply with Paragraph 28.2(1)(b) of the Patent Act. Maier disclosed the claimed subject matter before the claim date wherein the compounds are used as a herbicide.

Claims 1, 4, 7 and 8 and 11 do not comply with Paragraph 28.2(1)(b) of the Patent Act. Parsons et al. disclosed the claimed subject matter before the claim date wherein the compounds are used in the treatment of bacterial infections.

Claims 1 and 7-14 do not comply with Paragraph 28.2(1)(b) of the Patent Act. Both Kleiner and Reiter disclosed the claimed subject matter before the claim date. Note that the definition given in the description for alkylene on page 7, lines 26-28 includes the statement that "the hydrogen atoms may be replaced by other substituents". Therefore, the alkylene groups may be substituted and the use of the compounds disclosed by Reiter fall within the scope of claims 1 and 7-14.

Claims 12-14 do not comply with Section 28.3 of the Patent Act. The subject matter of these claims would have been obvious on the claim date to a person skilled in the art or science to which they pertain having regard to Parsons et al. Pharmaceutical preparations containing multiple active ingredients are well known in the art and there is no suggestion within the present description that the pharmaceutical preparations containing multiple active ingredients defined in claims 12-14 give surprising results. As such, it would be obvious to a person skilled in the art to prepare the pharmaceutical preparations containing multiple active ingredients defined in claims 12-14.

Claims 1-14 do not comply with Section 84 of the Patent Rules. The description fails to provide a sound line of reasoning for the utility of the compounds defined in claims 1-6 for the production of pharmaceutical preparations for the treatment of infections which are caused by the bacteria defined in claims 1 and 8, the viruses defined in claim 9 or the unicellular parasites defined in claim 10. There is no factual support in the application that leads to the conclusion that the subject matter of these claims would have the predicted utility. (Apotex Inc. v. Wellcome Foundation Ltd., 2002 SCC 77). There is no substantive support nor sound basis for predicting the utility of the compounds defined in claims 1-6 for the treatment of any infectious processes in humans and animals due to viruses, bacteria, fungi or parasites. Nor is there any substantive

support or sound prediction for the utility of the compounds of claims 1-6 for use as fungicide, bactericide or herbicide for plants.

Claim 1 does not comply with Section 84 of the Patent Rules because there is no support in the present description for the subject matter of claim 1. There is no support for A = alkenyl. However, there is support for A = alkenylene. In accordance with Section 38.2 of the Patent Act, the description may be amended to include the subject matter of the claims originally filed in the application.

Claim 1 is indefinite and does not comply with Subsection 27(4) of the Patent Act. The expression "and the pharmaceutically acceptable salts, esters and amides and salts of the esters" is indefinite. The nature of the salts, ester and salts of the esters is unclear. The only acidic moiety defined with the claimed compounds is the phosphonic acid and its salts and esters have already been defined earlier in claim 1.

Claim 1 is indefinite and does not comply with Subsection 27(4) of the Patent Act. The statement "or alternatively compounds which, on administration, provide the compounds to be used according to the invention as metabolites or breakdown products" is indefinite. The term "on administration" is unclear as it does not defined where the compound is administered while "the compounds to be used according to the invention" is indefinite since the nature of the compounds and the invention is indistinct. Finally, such a statement is of indeterminate scope as the compounds being claimed as not defined in explicit terms.

Claim 1 is indefinite and does not comply with Subsection 27(4) of the Patent Act. The term "the invention" has no antecedent.

Claims 1 and 2 are broader in scope than the teaching of the description. To comply with Section 84 of the Patent Rules, the claim must specify that the alkyl and hydroxyalkyl groups being defined contain up to 9 carbon atoms (page 6, lines 19-25).

Claims 1 and 2 are indefinite and do not comply with Subsection 27(4) of the Patent Act. Possible substituents included in the term "substituted" are not defined in explicit and distinct terms, thus causing the scope of the claims to be indeterminable.

Claims 1-3, 5, 8 and 14 are indefinite and do not comply with Subsection 27(4) of the Patent Act. These claims contain a Markush group. In order to be Markush claims, they must end with the conjunction "and" before the last element of the list. Note that in claim 1, the Markush groups used to define R_3, R_4, X_4 and the bacteria all lack the conjunction "and" before the last element of the list.

Claims 1-3 and 6 are indefinite and do not comply with Subsection 27(4) of the Patent Act. The functional groups "alkenyl", "alkynyl", "aryl", "acyl", "cycloalkyl", "aralkyl", "heterocyclic residue", "alkylene residue", "alkenyl residue", "hydroxyalkylene residue", "esters" and "amides" are not defined in explicit and distinct terms, thus causing the scope of the claims to be indeterminable.

Definitions for "alkenyl", "alkynyl", "aryl", "acyl", "cycloalkyl", "aralkyl", "heterocyclic residue". "alkylene residue", "alkenyl residue" and "hydroxyalkylene residue" given in the description are inadequate since they do not define the functional groups in explicit terms, instead using the indefinite expressions "includes", "preferably", "may be" and "such as".

Claims 1, 3, 5, 6, 8 and 9 do not comply with Subsection 27(4) of the Patent Act. The inclusion of "in particular", "preferably" and "such as" causes a lack of clarity. Preferred embodiments should be defined in separate dependent claims.

Claims 4 and 7 do not comply with Subsection 87(1) of the Patent Rules. Reference to preceding claims must be made by number.

Claim 7 is indefinite and does not comply with Subsection 27(4) of the Patent Act. It is unclear whether claim 7 is attempting to define all bacteria or only those defined within claim 1. If claim 7 is attempting to define all bacteria, then it does not comply with Section 87(3) of the Patent Rules as it would not be including all the limitations contained in the claim to which it refers to, namely claim 1.

Claim 9 is indefinite and does not comply with Subsection 27(4) of the Patent Act. The repeated inclusion of same virus within a Markush group results in indefiniteness. The following have been repeated: hepatitis viruses, hepatitis B virus, hepatitis D viruses, hepatitis A virus, hepatitis E virus and hepatitis C virus. This repetition must be removed.

Claim 9 is indefinite and does not comply with Subsection 27(4) of the Patent Act. "Wart" viruses is a layperson's term and should not be used to define the subject matter of the claims. In addition, the use of brackets causes ambiguity in terms of whether the applicant is attempting to claim papillomaviruses or all viruses that cause warts.

Claim 9 is indefinite and does not comply with Subsection 27(4) of the Patent Act. FSME virus should be ESME virus (early summer meningoencaphalitis).

Claim 9 is indefinite and does not comply with Subsection 27(4) of the Patent Act. Prions are defined as infectious proteinaceous particles of non-nucleic composition while viruses by definition contain genetic information. As such, the inclusion of prions within a Markush group defining viruses is inappropriate.

Claim 10 is indefinite and does not comply with Subsection 27(4) of the Patent Act. The use of the word "namely" causes the claim to become indefinite. It is unclear whether the applicant is attempting to define the subject matter of the claim broadly (unicellular parasites) or narrowly, limiting the subject matter to those unicellular parasites listed within the claim.

Claim 11 is indefinite and does not comply with Subsection 27(4) of the Patent Act. There is a lack of clarity as to whether the "at least one organophosphorus compound" refers to the organophosphorus compound defined in claims 1-6 or refers to an additional organophosphorus compound.

Claim 11 is indefinite and does not comply with Subsection 27(4) of the Patent Act because of the term "effective content". When such a functional statement occurs in a claim, the medicinal utility of the composition of matter must be stated or be inherent from the preamble of the claim.

Claim 13 is indefinite and does not comply with Subsection 27(4) of the Patent Act. The use of the word "moreover" results in ambiguity in claim 13. It is unclear whether the applicant is attempting to define the pharmaceutical preparation as comprising a pharmaceutical active substance (as defined in claim 12) and the constituent of claim 13.

Claims 13 and 14 are indefinite and do not comply with Subsection 27(4) of the Patent Act. As the compounds defined in claims 13 and 14 are pharmaceutically active substances, it is unclear whether the constituents defined in claims 13 and 14 are the same as the pharmaceutical active substances defined in claim 12.

Claim 14 is indefinite and does not comply with Subsection 27(4) of the Patent Act. Cefazolin, cefuroxime, cefoxitin, cefotazime and cefalexin are all specific members of the cephalosporin family of antibiotics. As such, the meaning of "cefazolin group", "cefuroxime group", "cefoxitin group", "cefotazime group" and "cefalexin group" is unclear.

Claim 14 is indefinite and does not comply with Subsection 27(4) of the Patent Act. "Conventional cephalosporins", "new broad spectrum oral cephalosporins", "other B-lactam antibiotics" and "other diaminopyrimidine sulfonamide combinations" are indefinite. The words "conventional", "new" and "other" are comparative terms for which there is no basis within claim 12.

Claim 14 is indefinite and does not comply with Subsection 27(4) of the Patent Act. The use of brackets around the term "quinolones" causes ambiguity in terms of whether the applicant is attempting to claim "quinolones" or all Gyrase inhibitors.

The description does not comply with Section 27(3) of the Patent Act for failing to fully describe the invention and its operation or use as contemplated by the inventor. The lack of supporting examples results in a lack of guidance so that someone skilled in the art would be able to put the invention into practice. As such, the description does not comply with Section 80(1)(f) of the Patent Rules as it does not set forth at least one mode contemplated by the inventor for carrying out the invention in terms of examples.

The description does not comply with Section 80(1)(c) of the Patent Rules. There is no description of the background art that can be regarded as important for the understanding, searching and examination of the invention.

Paragraph 80(1)(a) of the Patent Rules requires that the title be short and precise. "Use of aminoalkylphosphonic acid derivatives for producing medicaments for the therapeutic and prophylactic treatment of infections or as a fungicide, bactericide or herbicide for plants" is a suitable title.

The claims of Canadian applications must be complete independently of reference to the description. As such, reference to claim 1 on page 1 of the description is inappropriate and must be removed.

Under Subsection 81(3) of the Patent Rules, applicant must fully identify the documents referred to on page 18. A document so referred to should be identified at least by country, number and date for a published patent document, or by title, author, date, and source for non-patent documents. The document referred to as the "Red List" is not properly identified. In addition, the http internet address provided on page 18 defines a non-permanent electronic file and as such, does not constitute a permanently retrievable non-patent document. It is therefore an unacceptable source of documentation since access to the website is not guaranteed.

In view of the foregoing defects, the applicant is requisitioned to amend the application in order to comply with the Patent Act and the Patent Rules or to provide arguments as to why the application does comply.

Under Section 34 of the Patent Rules, any amendment made in response to this requisition must be accompanied by a statement explaining the nature thereof, and how it overcomes each of the above objections.

Under Section 29 of the Patent Rules, applicant is requisitioned to provide an identification of any prior art cited in respect of the corresponding United States and European Patent Office applications and the patent numbers, if granted. Amendment to avoid references cited abroad may expedite the prosecution. If the particulars are not available to the applicant, the reason why must be stated. The above requisitioned information must be provided regardless of the current status of the foreign applications.

Under Section 29 of the Patent Rules, applicant is requisitioned to provide particulars of conflict, opposition, re-examination or similar proceedings in which the corresponding United States and European Patent Office applications may have been involved.

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